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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,618	12/07/2004	Steven Melvyn Howdle	P70039USD	4009

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WASHINGTON, DC 20004

EXAMINER

HELM, CARALYNNE E

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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11/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,618

Applicant(s)

HOWDLE ET AL.

Examiner

CARALYNNE HELM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2009 and 11 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 26, 28, 30-42 and 44-59 is/are pending in the application.
- 4a) Of the above claim(s) 28, 30, 31, 34-36, 38, 41, 44, 46, 47, 50-52, 54 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 26, 32, 33, 37, 39, 40, 42, 45, 48, 49, 53, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

To summarize the current election, applicants elected, with traverse, Group I where the species includes deposition of dissolved/dispersed material by immersion and the deposit material is drugs and pharmaceutical products.

Claims 28, 30-31, 34-36, 38, 41, 44, 46-47, 50-52, 54, and 57-59 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 32-33, 37, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perman et al. (previously cited).

The instant claims recite a method of preparing a polymer composite. Perman et al. teach the claimed method where a carrier fluid is combined with an impregnation material (deposition materials) and applied to a polymer such that the polymer is covered (deposition matter at surface of polymer) (see column 4 lines 43-50). A supercritical fluid is added to the system, swelling the polymer and impregnating the impregnation material into the polymer (see column 3 line 52-column 4 line 13; instant claim 27). The supercritical fluid is then removed from the system (see column 4 lines 8-13). Biologically active drugs, including nucleotides, vitamins, and proteins, are particularly preferred impregnation materials (see column 6 line 61-column 7 line 4;

instant claims 39-40). In addition, Perman et al. teach the drying of the carrier fluid from the impregnated polymer by blotting (see column 17 lines 3-7). According to MPEP 2111.01 II, "it is improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order." Neither the specification or the recitation of the claims strictly require a specific order for the steps in the method, therefore the teachings of Perman et al. meet the limitations of the claimed process (see instant claim 25). In addition, the absence of agitation is taught by Perman et al. when a solution of impregnation material is employed (see column 10 lines 26-31; instant claim 37). Perman et al. also teaches the immersion of the polymer in the impregnation material and carrier fluid for 17 hours (see column 16 line 66-column 17 line 5; instant claim 32). Therefore claims 25, 27, 29, 32-33, 37, and 39-40 are obvious over Perman et al.

Claims 25, 26, 42-43, 45, 48-49, 53, and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perman et al. as applied to claims 25, 27, 29, 32-33, 37, and 39-40 above, and further in view of Colombo et al. (previously cited).

Perman et al. makes obvious the method as recited in claims 25 and 42 as well as the details of the recited dependent claims 43, 45, 48-49, 53, and 55-56 but does not teach the relative amount of impregnated material on the polymer.

Colombo et al. teach a method of impregnating a polymer with a drug using a carrier fluid and supercritical fluid in a process as taught by Perman et al. (see column 3

lines 38-49 and column 5 lines 3-5). Colombo et al. goes on to teach a 1:10 to 1:1 ratio of active to polymer in the impregnated material (see column 4 lines 49-55; instant claims 26 and 42). Therefore it would have been obvious for one of ordinary skill in the art at the time of the invention to use the teachings of Colombo et al. to determine the proportion of impregnation material to include in the polymer of Perman et al. Thus claims 25, 26, 42-43, 45, 48-49, 53, and 55-56 are obvious over Perman et al. in view of Colombo et al.

Response to Arguments

Applicants' arguments, filed July 14, 2009 and August 11, 2009, have been fully considered but they are not deemed to be persuasive.

Applicants' amendments relative to the rejections under 35 USC 112 first and second paragraph are noted and these rejections are hereby withdrawn.

Applicants' arguments focusing on the order of the claimed steps in response the rejections made under 35 USC 103(a) are not persuasive. MPEP 2144.04IVC highlights *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), noting that the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. Applicants have not provided any results indicating that the recited ordering of the claimed process steps yields a new or unexpected result as compared to a different ordering. Therefore the instant invention is obvious over Perman et al.

(regarding claims 25, 27, 29, 32-33, 37, and 39-40) or Perman et al. in view of Columbo et al. (regarding claims 25, 26, 42-43, 45, 48-49, 53, and 55-56).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CARALYNNE HELM** whose telephone number is

(571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615